REMARKS

THE CLAIM AMENDMENTS

Claim 1 has been amended to correct a grammatical inconsistency and as such, adds no new matter to the application.

IN RE THE EXAMINER'S SUGGESTION TO CHANGE "CELLULOSIC" TO "CELLULOSE"

Applicants acknowledge the Examiner's suggestion to change the term "cellulosic polymers" to "cellulose polymers," but again disagree that this change will improve the application; on the contrary, applicants are of the opinion that such a change in terminology would be pernicious to the meaning of the claims reciting this term by rendering the claims indefinite.

The application specifically provides a definition for "cellulosic polymers." Because applicants are entitled to be their own lexicographer, the use of this term in the claims exactly as it appears in the application, provides a distinct meaning to the claim term that would not lead the ordinary artisan to wonder what is meant by the term. Were applicants to change the term "cellulosic polymers" to "cellulose polymers" as suggested by the Examiner, applicants would risk renouncing the application of the definition for "cellulosic polymers" that is set forth in the specification; something which applicants vehemently do not want to do.

Further, applicants do not understand the Examiner's reasoning for wanting to change this term. The Examiner has not rejected this term as indefinite and is not objecting to the use of the term as informal; rather, the Examiner is suggesting that applicants change their chosen claim language to a claim term that the Examiner would prefer to see, without a clear reason for making the suggestion. In particular, the Examiner asserts that the term cellulosic "includes elements that are not disclosed by the term." Applicants do not understand what the Examiner means by this statement and thus, cannot respond to it. If the Examiner could explain the meaning of this statement, applicant might be able to provide the Examiner with an explanation to clarify any confusion that the Examiner has with respect to applicants' use of the term "cellulosic." The Examiner also asserts that it is not clear "what celluloses are included in the term 'cellulosic.'" In response to this statement, applicants direct the Examiner's attention to page 19, lines 4-23 of the specification, which discloses over half a page of celluloses that are contemplated within the term "cellulosic."

From a legal standpoint, it is well-established that an applicant for a patent may be his or her own lexicographer and is entitled to use claim terms that they expressly define in the specification. Further, it is unarguable that an applicant for a patent is under no obligation to adopt language preferred by the

Examiner, especially where applicants have properly defined the term in the specification and have disclosed an ample number of examples for the ordinary artisan to use for guidance. Thus, because adopting the Examiner's language may jeopardize applicants' intended claim meaning and risks creating an estoppel towards the application of a definition provided for the term, applicants respectfully defer from adopting the Examiner's suggested language.

THE LEGAL STANDARD FOR ESTABLISHING A *PRIMA FACIE* CASE

The *prima facie* case is a procedural tool which, as used in patent examination, means not only that the evidence of the prior art would reasonably allow the conclusion the Examiner seeks, but also that the prior art compels such a conclusion if the applicant produces no evidence or argument to rebut it. *In re Spada,* 911 F.2d 705 (Fed. Cir. 1990). If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more, the applicant is entitled to a grant of the patent. *In re Oetiker,* 977 F.2d 1443 (Fed. Cir. 1992).

The Examiner's *prima facie* case is premised on anticipation rejections; accordingly, the Examiner must show that each and every element of the claimed invention is found, either expressly or inherently, in a single prior art reference. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565, 24 USPQ2d 1321, 1326 (Fed. Cir. 1992).

RESPONSE TO EXAMINER'S REFUSAL TO CONSIDER THE PROCESS STEP OF CLAIM 1

Claim 1 is a product-by-process claim; it recites that the gastric-retentive erodible dosage form is prepared by the process of a disintegration test to optimize the dosage form.

In the Office Action under reply, the Examiner asserts that the claimed process does not impart any patentable subject matter into the claims, applicants respectfully disagree. In support, applicants respectfully direct the Examiner's attention to MPEP § 2113, which provides the following guidance on when a process step serves to render a product claim patentably distinct over the prior art:

> The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. *See, e.g., In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place,"

"press fitted," and "etched" are capable of construction as structural limitations).

The dosage form of the claimed invention are prepared using a disintegration test, which imparts *a unique structural characteristic to the claimed dosage forms*; specifically, the disintegration test determines the release profile of the active agent. Without subjecting the active agent to the disintegration test, the dosage form will have a different release profile than that of the claimed invention. This important feature of the claimed invention is discussed in the specification at, *inter alia*, page 3, lines 1-7; page 3, line 10 to page 11, line 8; page 13, lines 12-16; page 13, line 27 to page 14, line 11; page 16, lines 6-27; Examples 1 and 2.

Because the claims are specifically worded to include the disintegration test as a process step inherently associated with the recited dosage form, the Examiner is obligated to consider the recitation of the application of the disintegration test when examining the claims. *In re Garnero, supra.* In light of the foregoing, the Examiner's assertion that the recitation of the use of the disintegration test to optimize the dosage form has no weight is not proper in light of established patent law principles.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

Claims 1-9, 12-16, 18-23, 26-34, 36-40, and 45-54 stand rejected under 35 U.S.C. § 102(b) as anticipated by Shell et al. (U.S. Patent No. 5,972,389; hereinafter "Shell '389").

Claims 1-7, 10, 12, 17-23, and 45-49 stand rejected under 35 U.S.C. § 102(b) as anticipated by Shell et al. (U.S. Patent No. 5,007,790; hereinafter "Shell '790").

Claims 1-7, 10, 17-22, and 39 stand rejected under 35 U.S.C. § 102(b) as anticipated by Uemura et al. (U.S. Patent No. 4,695,467).

These rejections are respectfully traversed.

As noted in the previous Amendment and as set forth above, Shell '389, Shell '790, and Uemura et al. do ***not*** teach or suggest the use of a disintegration test to optimize the dosage form disclosed therein. Since each of these three reference do ***not*** teach or suggest this important structural element, it follows that Shell '389, Shell '790, and Uemura et al. do ***not*** anticipate the claimed invention.

CLAIM REJECTION UNDER 35 U.S.C. § 102(e)

Claims 1, 6-8, 11, 23-25, 30, 34, and 35 stand rejected under 35 U.S.C. § 102(e) as anticipated by Vandecruys et al. (U.S. Patent No. 6,667,069). This rejection is respectfully traversed.

Vandecruys et al. teach a pregelatinized starch to prevent dose-dumping from a hydrophilic controlled release formulation. Preferred hydrophilic polymers include hydroxypropyl cellulose and hydroxypropyl methylcellulose.

The Examiner asserts that Vandecruys et al. meets the limitations of the claimed invention, but the Examiner is wrong on this matter, the claimed invention does ***not*** read on Vandecruys et al. The Examiner appears to be of the opinion that the only element of claim 1 is the recitation of a biocompatible, hydrophilic polymer and is applying references to the claimed invention as if this is the only recited element. On this matter, applicants remind the Examiner that the claimed invention is ***not*** limited to a biocompatible, hydrophilic polymer with nothing more. The claimed invention recites the following elements, all of which ***must*** be subject to examination:

1. an erodible, gastric-retentive drug dosage form for administering a pharmacologically active agent to the stomach, duodenum, and upper small intestine of a patient, the dosage form comprising the pharmacologically active agent;
2. incorporated in a matrix of at least one biocompatible, hydrophilic polymer that:
3. swells in the presence of water in gastric fluid such that the size of the dosage form is sufficiently increased to provide gastric retention in the stomach of a patient in whom the fed mode has been induced;
4. gradually erodes within the gastrointestinal tract over a determinable time period, and
5. releases the active agent throughout the determinable time period;
6. wherein the dosage form is optimized by subjecting the dosage form to a disintegration test for an extended period of time such that the dosage form has an *in vitro* active agent release profile that correlates to a desired *in vivo* active agent release profile for the dosage form.

As explained above, to establish a *prima facie* of patentability, the Examiner ***must*** demonstrate that each of the elements recited in the claims of the instant application is disclosed, either expressly or inherently, in the prior art. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, supra.* Since Vandecruys et al. does ***not*** teach or suggest that the hydrophilic polymer is optimized through the use of a disintegration test, it follows that Vandecruys et al., just like Shell '369, Shell '790, and Uemura et al. do not anticipate the claimed invention. Accordingly, applicants respectfully request withdrawal of this rejection.

CONCLUSION

The foregoing discussion sets forth a detailed explanation of the law that must be applied to this application and the elements that are missing from the prior art. Applicants submit that were the Examiner to consider each element of the claims as is required for the *prima facie* case, the Examiner will be led to the conclusion that the claimed invention is not anticipated by any of the cited references. Because the claimed invention is not rendered obvious by Shell '389, Shell '790, Uemura et al., or Vandecruys et al., respectfully request reconsideration and withdrawal of all claim rejections and passage of this application to issue. *See, In re Oetiker, supra.*

Should the Examiner wish to contact the undersigned to discuss this response or the application in general, she is welcome to do so at 650-330-4913 or at canaan@reedpatent.com.

Respectfully submitted,

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